

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

In re: Rosuvastatin Calcium Patent Litigation	Civ. No. 08-md-1949 <b>REDACTED VERSION DI 282</b>
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Mylan Pharmaceuticals Inc., Defendant.	Civ. No. 07-805-JJF-LPS <b>REDACTED VERSION DI 179</b>
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sun Pharmaceutical Industries Ltd., Defendant.	Civ. No. 07-806-JJF-LPS <b>REDACTED VERSION DI 181</b>
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sandoz Inc., Defendant.	Civ. No. 07-807-JJF-LPS <b>REDACTED VERSION DI 197</b>

<p>AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs,</p> <p>v.</p> <p>Par Pharmaceutical, Inc., Defendant.</p>	<p>Civ. No. 07-808-JJF-LPS <b>REDACTED VERSION DI 176</b></p>
<p>AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs,</p> <p>v.</p> <p>Apotex Inc. and Apotex Corp., Defendants.</p>	<p>Civ. No. 07-809-JJF-LPS <b>REDACTED VERSION DI 201</b></p>
<p>AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs,</p> <p>v.</p> <p>Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.</p>	<p>Civ. No. 07-810-JJF-LPS <b>REDACTED VERSION DI 237</b></p>

<p>AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,</p> <p>Plaintiffs,</p> <p>v.</p> <p>Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc.,</p> <p>Defendants.</p>	<p>Civ. No. 07-811-JJF-LPS <b>REDACTED VERSION DI 201</b></p>
<p>AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,</p> <p>Plaintiffs,</p> <p>v.</p> <p>Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited Inc.,</p> <p>Defendants.</p>	<p>Civ. No. 08-359-JJF-LPS <b>REDACTED VERSION DI 158</b></p>

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha,  Plaintiffs,  v.  Teva Pharmaceuticals USA  Defendant.	Civ. No. 08-426-JJF-LPS <b>REDACTED VERSION DI 164</b>
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**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR  
SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT**

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This memorandum supports Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. (collectively “AstraZeneca”), and Shionogi Seiyaku Kabushiki Kaisha’s (“Shionogi”) Motion for Summary Judgment of No Inequitable Conduct.

## **INTRODUCTION**

AstraZeneca and Shionogi seek summary judgment against Defendants’ baseless defense that U.S. Patent No. RE37,314 (“the ‘314 patent”) is unenforceable due to inequitable conduct allegedly committed by Shionogi and its U.S. patent counsel.<sup>1</sup> The ‘314 patent covers the active ingredient, rosuvastatin, in Plaintiffs’ blockbuster drug, Crestor®. Defendants allege that Shionogi and its counsel deliberately and intentionally withheld material prior art publications from the United States Patent and Trademark Office (“USPTO”) while prosecuting the ‘440 patent application. Neither the evidence nor any reasonable inferences from it supports Defendants’ hindsight-inspired allegations.

For over a year, the parties have engaged in broad spectrum discovery of Shionogi’s records. Shionogi even produced its privileged communications with its lawyers about the rosuvastatin invention and prosecution of the rosuvastatin patent applications. Defendants deposed 22 current and former Shionogi employees (some on multiple occasions), including Shionogi’s U.S. patent counsel and current and former members of Shionogi’s Patent Department.

The evidence is fully developed. Undisputed facts and the most reasonable inferences from that evidence show that the non-disclosure of prior art to the USPTO was due to lack of knowledge, justifiable reliance on others, innocent mistake, or simple negligence. No clear and convincing evidence of intent to deceive the USPTO exists. No one deliberately decided to

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<sup>1</sup> The ‘314 patent is a reissue of original U.S. Patent No. 5,260,440 (“the ‘440 patent”).



conceal material information. Defendants' inequitable conduct allegations are unfounded, and they require acceptance of unreasonably strained factual inferences. And as a result, they are legally unsustainable. Plaintiffs therefore move for summary judgment of no inequitable conduct.

### **NATURE AND STAGE OF THE PROCEEDINGS**

Plaintiffs initiated these eight patent infringement actions against Defendants, who each seek regulatory approval to market generic copies of Crestor<sup>®</sup>, Plaintiffs' cholesterol-lowering drug. These related actions, filed in this and other Districts, were consolidated in Delaware by the Judicial Panel on Multidistrict Litigation for pretrial proceedings. (C.A. No. 08-md-1949.) Fact discovery has ended, and the parties are engaged in expert discovery.

Each Defendant alleges that the '314 patent is invalid in view of the prior art or unenforceable due to inequitable conduct. Certain Defendants have admitted infringement of the '314 patent, while others allege noninfringement. Plaintiffs' Motion only addresses Defendants' allegations of inequitable conduct.

### **SUMMARY OF ARGUMENT**

For Defendants to establish inequitable conduct at trial, they must prove by clear and convincing evidence *both* elements of the defense—materiality of the non-disclosed information and intent to deceive. But for Plaintiffs to succeed on this Motion, they need only demonstrate that, based on the undisputed facts, there is no clear and convincing evidence of *either* materiality or deceptive intent.

This Motion addresses only the intent element. Direct evidence of deceitful intent is typically unavailable. Certainly that is true here. Deceitful intent can be inferred; but the inference must be reasonable and arise solely from underlying facts proven with clear and

convincing evidence—that is, deceitful intent must be the *single* most reasonable inference from those facts. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366-67 (Fed. Cir. 2008); *Cordis Corp. v. Boston Scientific Corp.*, No. 98-197-SLR, 2009 WL 2437236, \*5 (D. Del. Aug. 10, 2009) (court errs in overlooking equally reasonable inferences of no inequitable conduct). And the evidence must clearly and convincingly show that a person “made a deliberate decision to withhold a known material reference.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)

Extensive and meticulous year-long discovery yielded no clear and convincing evidence establishing deceitful intent under the *Star Scientific* test on the part of any of the eight individuals substantively involved in the filing or prosecution of the application for the '440 patent.<sup>2</sup> Instead, the undisputed facts establish that the non-disclosure of certain prior art to the USPTO was due to lack of knowledge, justifiable reliance on others, innocent mistake, or simple negligence. No evidence suggests any deliberate decision on the part of the involved individuals to withhold prior art from the USPTO.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>2</sup> The eight individuals include the four named Shionogi employee-inventors (Drs. Hirai and Koike and Messrs. Ishiba and Watanabe); three members of Shionogi's Patent Department (Ms. Tomoko Kitamura, Mr. Takashi Shibata, and Ms. Masako Shimizu); and Shionogi's outside U.S. patent counsel (Mr. Matthew Jacob).

[REDACTED]

[REDACTED]

Ms. Kitamura, a member of the Shionogi Patent Department, [REDACTED]  
[REDACTED].<sup>3</sup> But, she left Shionogi about one month after the filing of  
the U.S. application. She had already resigned and left Shionogi when a Search Report issued by  
the EPO citing a prior art reference by Sandoz arrived at Shionogi. [REDACTED]  
[REDACTED], she left the company before the normal time for disclosing prior art to the  
USPTO. [REDACTED]  
[REDACTED]

Ms. Kitamura's departure, unfortunately, contributed to the failure to disclose prior art to  
the USPTO. Shortly after Ms. Kitamura's resignation and departure, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Ms. Shimizu had no knowledge of the non-disclosed prior art. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] As a result, the prior art was never cited to the USPTO.

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<sup>3</sup> [REDACTED]  
[REDACTED]

During the relevant time, Mr. Shibata, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These undisputed facts simply do not support an inference of deceitful intent. There was no inequitable conduct.

**Concise Statement of Undisputed Facts Dictating a Finding of No Inequitable Conduct<sup>4</sup>**

The following summarizes the undisputed facts from which the only reasonable inference that can be drawn is that the non-disclosure of prior art resulted from lack of knowledge, justifiable reliance on others, innocent mistake, or simple negligence.

[REDACTED]

2. [REDACTED]

[REDACTED] The Japanese patent application was filed in July 1991—eleven months before the U.S. patent application was filed in June 1992. (UF 7.)

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<sup>4</sup> Submitted herewith in support of Plaintiffs' motion is the declaration of Mary W. Bourke and its exhibits, including as Exhibit 1, Plaintiffs' Statement of Undisputed Material Facts (cited herein as "UF").



patent law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is “genuine” only if a reasonable jury could return a verdict in favor of the non-movant. *Id.* If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. *Id.* at 249-50; *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1126, 1134 (E.D. Cal. 2002) (citing *Anderson*, 477 U.S. at 248 ).

A patent is presumed valid and enforceable, and a challenger must prove both invalidity and unenforceability by clear and convincing evidence. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004). Clear and convincing evidence is evidence that “proves in the mind of the trier of fact “an abiding conviction that the truth of [the] factual contentions are [sic] ‘highly probable.’” *Intel Corp. v. United States Int’l Trade Comm’n*, 946 F.2d 821, 830 (Fed. Cir. 1991) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

In a summary judgment motion, a court “must view the evidence presented through the prism of the substantive evidentiary burden.” *Anderson*, 477 U.S. at 254. Therefore, Plaintiffs’ burden on this Motion simply is to demonstrate that Defendants cannot prove inequitable conduct by clear and convincing evidence.

Summary judgment of no inequitable conduct is entirely proper and numerous examples abound. In *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353, 1362 (Fed. Cir. 2008), the Federal Circuit affirmed summary judgment of no inequitable conduct where the patentee did not disclose a copending patent application to a drug compound that arguably was structurally similar to the claimed drug compound because there was no evidence of deceptive intent. *See also Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379-80 (Fed. Cir. 2002) (affirming finding of summary judgment of no inequitable conduct because the undisclosed test

data was of questionable materiality, and the infringer had failed to show the requisite high level of intent to deceive).

In *Tenneco Automotive Operating Co. v. Visteon Corp.*, 375 F. Supp. 2d 366, 374-75 (D. Del. 2005), this Court granted summary judgment of no inequitable conduct where defendants failed to prove that a material reference was withheld with knowledge of the reference or an intent to deceive. Similarly, in *Matsushita Electrical Ind. Co. v. Cinram Int'l, Inc.*, 299 F. Supp. 2d 348, 360-61 (D. Del. 2004), summary judgment of no inequitable conduct was granted where there was no evidence that an inventor knew of presumed material information or that he intentionally withheld it from the USPTO.

In a recent case involving ANDA submissions for the anti-psychotic drug, Seroquel®, the court granted summary judgment of no inequitable conduct at the conclusion of extensive fact discovery. Summary judgment was based on defendants' lack of evidence and assertion of unreasonable inferences concerning materiality and intent. *AstraZeneca Pharm. LP v. Teva Pharmaceuticals USA*, 567 F. Supp. 2d 683, 692-701 (D.N.J. 2008).

### **The Law of Inequitable Conduct**

To successfully prove inequitable conduct, Defendants must present “evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [USPTO].” *Cargill, Inc. v. Cambra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007) (citing *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006)). A charge of inequitable conduct must be proven by clear and convincing evidence against an individual person, not a collection of people or entity. *See FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 525 n.5 (Fed. Cir. 1987) (rejecting inequitable conduct claim asserted against a “great number of people”

and noting “[o]ne attempting to prove inequitable conduct must prove by clear and convincing evidence that the conduct of the person *charged* was inequitable.”) (emphasis in original).

Materiality and intent are separate threshold elements of a claim of inequitable conduct; each requiring independent proof by clear and convincing evidence. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d at 1365; *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362 (Fed. Cir. 2003); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc). Failing to prove either element dooms any alleged inequitable conduct claim. *Dayco Products*, 329 F.3d at 1362-63; *Purdue Pharma, L.P. v. Endo Pharm., Inc.*, 438 F.3d 1123, 1134 (Fed. Cir. 2006) (“[M]ateriality does not presume intent”); *Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc.*, 04-1689, 06-757, 2006 WL 1517749, \*3 (D.N.J. May 30, 2006) (there must be some independent evidence, *other* than materiality, of an intent to deceive).

And even if this elevated evidentiary burden is met as to both elements, the Court must still balance the equities to determine whether the applicant’s conduct before the USPTO was egregious enough to warrant holding the entire patent unenforceable. *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004). Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the Court may still decline to render the patent unenforceable.

Strictly enforcing the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe—a patentee can lose the entire patent even if every claim clearly meets every requirement of patentability. As the Federal Circuit warned in *Star Scientific*:

Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information



to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

537 F.3d at 1366. This Court recently explained, “There can be no doubt that the Federal Circuit proceeds with great caution when it comes to declaring a patent unenforceable due to inequitable conduct.” *Cordis*, 2009 WL 2437236 at \*3 (citing *Star Scientific*, 537 F.3d at 1357).

As to intent to deceive, the Federal Circuit has emphasized that “materiality does not presume intent, which is a separate and essential component of inequitable conduct,” *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). Indeed:

[T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to . . . mislead[ ] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.

*Molins*, 48 F.3d at 1181 (emphases added); *see also FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (“‘Inequitable conduct’ is not, or should not be, a magic incantation to be asserted against every patentee. . . . To be guilty of inequitable conduct, one must have intended to act inequitably.”). Thus, to prevail on the defense, Defendants must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO. *Id.*; *see also Kingsdown*, 863 F.2d at 876 (holding even gross negligence insufficient to prove intent to deceive).

Because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. *Cargill*, 476 F.3d at 1364. But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the

deceptive intent requirement. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006) (“The predicate facts must be proven by clear and convincing evidence.”).

To meet the clear and convincing standard, compelling factual evidence must support an inference of intent to deceive; the inference must not only be *reasonable* in light of that evidence, but it must also be the *single most reasonable inference* to be drawn from the evidence. *Star Scientific*, 537 F.3d at 1366-67 (emphasis added) (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (citation omitted)). The Federal Circuit recently reaffirmed that an inference of intent to deceive must be “‘*the single most reasonable inference* to be drawn from the evidence to meet the clear and convincing standard.’” *Exergen Co. v. Wal-Mart Stores, Inc.*, Nos. 2006-1491 & 2007-1180, 2009 WL 2366535, \*16 n.5 (Fed. Cir. August 4, 2009) (quoting *Star Scientific*, 537 F.3d at 1366) (emphasis in original). “Wherever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.” *Scanner Techs.*, 528 F.3d at 1376.

Thus, in circumstances where “the inferences argued [by the patentee] are supported by evidence of record and are as reasonable as those inferences argued by [the accused infringer], . . . it would be clear error . . . to imbue [the patentee’s] conduct with deceptive intent. . . .” *Cordis*, 2009 WL 2437236 at \*5 (citing *Scanner Techs.*, 528 F.3d at 1376). And, “[i]f a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities or how it might balance them.” *Star Scientific*, 537 F.3d at 1367.

**None of the Four Inventors Intended to Deceive the USPTO**

The '314 patent names four inventors. (UF 1.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Defendants may assert that Dr. Hirai and the inventors failed to disclose two known scientific publications, one by Beck et al. and the other by Roth et al. (UF 5.) There is no evidence that either reference discloses the claimed compounds; they do not. (*Id.*) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] There is no evidence that Dr. Hirai or any of the other three inventors made deliberate decisions to withhold prior art from the USPTO. *Molins*, 48 F.3d at 1181.

\_\_\_\_\_

(UF 7.) [REDACTED]

\_\_\_\_\_

1. **PROPOSED** **REVISIONS** **TO** **THE** **2010** **STATE** **BUDGET** **FOR** **THE** **2011** **FISCAL** **YEAR** **ARE** **AS** **FOLLOWS:**

\_\_\_\_\_

[illegible]

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<sup>5</sup> Ms. Kitamura has since married and is now "Ms. Ozawa."

**Ms. Shimizu Did Not Intend to Deceive the USPTO**

After Ms. Kitamura left Shionogi, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

There is no evidence that she knew about or received any information relating to any of

[REDACTED]

[REDACTED] There is no evidence that she knew about or received any information relating [REDACTED]

[REDACTED]. And there is no evidence that she had any involvement with [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

No rejections in the U.S. case required her to consider (or search for) any prior art. (UF 20.) Nothing in the U.S. prosecution required a review of the counterpart European or Japanese application files. (*Id.*) [REDACTED], Ms. Shimizu could not have made a deliberate decision to withhold the prior art from the USPTO with the requisite specific intent to deceive. *FMC Corp.*, 835 F.2d at 1415 (patentee can successfully rebut an inequitable conduct charge by, *inter alia*, “showing that the applicant did not know of that art or information” or that the failure to disclose “did not result from an intent to deceive”); *see also Tenneco*, 375 F. Supp. 2d at 374-75.

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<sup>6</sup> Ms. Shimizu has since married and is now “Ms. Washio.”

[REDACTED]

[REDACTED]

[REDACTED]. See *Cordis*, 2009 WL 2437236 at \*5 (deliberate ignorance requires proof that a practitioner “purposefully neglected [her] responsibility of candor to the PTO by ‘putting [her] head[] in the sand’ regarding the prior art”) (quoting *Star Scientific*, 537 F.3d at 1366). The most her failure to investigate can prove is that she made a mistake. Proof of a mistake is not proof of intent to deceive. Ms. Shimizu [REDACTED] [REDACTED]—she was inexpert in matters of U.S. law and practice. Any negligence on her part does not equal intent to deceive. *Kingsdown*, 863 F.2d at 876 (holding even gross negligence insufficient to prove intent to deceive).

**Mr. Jacob Did Not Intend to Deceive the USPTO**

Mr. Matthew Jacob, Shionogi’s U.S. patent lawyer who filed the ‘440 patent application and communicated directly with the USPTO, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Because Mr. Jacob was not aware of the prior art, he could not have formed a specific intent to withhold it from the USPTO. *FMC Corp.*, 835 F.2d at 1415.

**Mr. Shibata Did Not Intend to Deceive the USPTO**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*)

Decisions made during that time had unfortunate consequences. For example, the ESR, a routine, non-substantive EPO prosecution communication, arrived at Shionogi's Patent Department in October 1992, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] While

perhaps unwise and ill-conceived, none of these acts, failures to act, or assumptions constitute or infer an intent to deceive.

To the contrary, contemporaneous evidence demonstrates Mr. Shibata's belief that the prior art *had* been submitted to the USPTO— [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

When confronted by Shionogi's failure to disclose prior art to the USPTO, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(UF 24.)

There is no evidence that [REDACTED], Mr. Shibata deliberately concealed the ESR or other prior art from Ms. Shimizu or the USPTO. *See In re Harita*, 847 F.2d 801, 809 (Fed. Cir. 1988) ("as an ideal Japanese patent agent he *should have known* more about U.S. PTO rules and practice and developing case law, but *we deal here with the realities of what actually happened*") (emphasis added); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) ("Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO."). There is no evidence of any misrepresentations during the prosecution



before the USPTO, nor is there any evidence of any deliberate scheming. *Harita*, 847 F.2d at 808-09.

The single most reasonable inference from the evidence is that Mr. Shibata justifiably relied on others, perhaps did not make the best decisions, or made innocent mistakes. To ignore this reasonable inference is legal error. *Scanner Techs.*, 528 F.3d at 1376 (“[w]henver evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”); *see also Cordis*, 2009 WL 2437236 at \*5.

**The ‘440 Patent Prosecution Was not Misrepresented in the ‘314 Reissue Application**

As part of the reissue application for the ‘314 patent, Shionogi stated that the ‘440 patent claimed more than Shionogi had a right to claim in view of the Sandoz prior art and that Shionogi was seeking to reissue the patent without that error. (UF 29.) Shionogi certified to the USPTO that the error was not the result of deceptive intent. (*Id.*) Defendants allege that this certification was false and misleading and that the ‘314 patent was procured through inequitable conduct.

As discussed above, the errors in the ‘440 patent application were not the result of deceptive intent. Additionally, all of the prior art in contention in this litigation was disclosed to and considered by the USPTO during the ‘314 patent reissue prosecution. (UF 30.) Defendants can sustain no other substantive allegations of inequitable conduct concerning the ‘314 patent prosecution sufficient to satisfy their burden of proof.

## CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for Summary Judgment of No Inequitable Conduct.

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